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First Named Inventor:	CLARKE, GRAHAM M.		
Application No.:	10/621620	Confirmation No.:	1875
Filed:	July 17, 2003	Group Art Unit	
Title:	MICRONEEDLE DEVICES AND MICRONEEDLE DELIVERY APPARATUS		

BRIEF ON APPEAL

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P.O. Box 1450
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August 3, 2010 /Rebecca C. Bode/

Date Signed by: Rebecca C. Bode

Dear Sir:

This is an appeal from the Office Action mailed on January 14, 2010, rejecting claims 1–8 and 17.

Fees

☒ Any required fee under 37 CFR § 41.20(b)(2) will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.17 which may be required to Deposit Account No. 13-3723.

☒ Please charge any additional fees associated with the prosecution of this application to Deposit Account No. 13-3723. This authorization includes the fee for any necessary extension of time under 37 CFR § 1.136(a). To the extent any such extension should become necessary, it is hereby requested.

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A Notice of Appeal in this application was mailed on May 11, 2010, and was received in the USPTO on May 11, 2010. A request for a one month extension of time is filed concurrently with this Brief on Appeal.

REAL PARTY IN INTEREST

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

STATUS OF CLAIMS

Claims 1–8 and 17 are pending, each of which has been twice rejected, most recently by Examiner's Office Action dated January 14, 2010, from which Appellant appeals. Claims 9–16 and 18–40 have been cancelled.

The pending claims 1–8 and 17 are being appealed and may be found in the attached Claims Appendix.

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STATUS OF AMENDMENTS

No amendments have been filed after the final rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

The claims at issue concern microneedle drug delivery devices having one or more tapered (e.g., pyramid shaped) microneedles with a truncated, flat tip having a claimed surface area. The term microneedle is found in the description (page 7, first paragraph) as having a length of up to 500 micrometers. The flat tip having the claimed surface area reduces fractures of the microneedles, while still permitting penetration through the stratum corneum (page 2, lines 9–12).

There are two independent claims on appeal, claims 1 and 8.

Claim 1 calls for a microneedle device (10) comprising a substrate (20) comprising a first major surface (22); and at least one microneedle (30) projecting from the first major surface (22) of the substrate (20), the at least one microneedle (30) comprising a base (34) proximate the first

major surface (22) of the substrate (20), wherein the at least one microneedle (30) is tapered from the base (34) to a flat tip (32) distal from the base (34) such that the at least one microneedle (30) comprises a truncated tapered shape; wherein the flat tip (32) comprises a surface area measured in a plane aligned with the base of 20 square micrometers or more and 250 square micrometers or less. See, e.g., specification page 2, lines 25 to 31; and page 7, line 13 to page 8, line 7.

Claim 8 requires each microneedle to be formed of one or more polymers (see specification page 3, line 8), the flat tip comprises a surface area measured in a plane aligned with the base of 20 square micrometers or more and 100 square micrometers or less, the base of each microneedle of the plurality of microneedles comprises a base area of 900 square micrometers or more (page 3, lines 11 to 13), and each microneedle of the plurality of microneedles has an aspect ratio of at least 3:1 (page 3, line 16).

As required by 37 C.F.R. § 41.37(c)(1)(v), a concise explanation of the subject matter defined in each of the independent claims involved in the appeal is provided herein. Appellant notes that representative subject matter is identified for each of these claims; however, the abundance of supporting subject matter in the application prohibits identifying all textual and diagrammatic references to each claimed recitation. Appellant thus submits that other application subject matter, which supports the claims but is not specifically identified above, may be found elsewhere in the application. Appellant further notes that this summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to the appended claims and their legal equivalents for a complete statement of the invention.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1–7 and 17 stand rejected under 35 USC § 102(e), as purportedly anticipated by Sherman et al. (US 2002/0020688).

ARGUMENT

The issue on appeal is straightforward: does Sherman et al. disclose truncated microneedles having a flat tip having a surface area of at least 20 square micrometers, as required by the present claims? Or, more precisely, can something without a surface have a surface area?

Applicants respectfully submit that Figure 11 of Sherman et al., relied upon by the Examiner, clearly discloses a microneedle structure having a hollow tip, thus, arguably having a

cross-sectional area, but no surface and therefore no surface area. Moreover, where Sherman et al. does disclose microneedles without hollow tips, they appear invariably to have conventional sharply pointed tips. For example, the Examiner cites paragraph 0088, but that paragraph actually supports Applicants' position (emphasis added):

> **[0088] Fig. 15A** represents an alternative embodiment in which a microneedle array **290** comprises "solid" microneedles **292** and **294**, rather than hollow microneedles as seen at **282** and **284** on FIG. 15. These solid microneedles **292** and **294** are formed by a similar mold as viewed on **FIG. 12**, but with the micropillars **222** and **224** removed from this mold, and a change in shape of the microholes **213** and **217**. This simple change allows the solid microneedles to be formed within conical microholes (not shown on **FIG. 12**), and produces a pointed conical shape, as exhibited by the outer conical wall **250** and **252** for microneedle **292**, with a top pointed surface at **296**. Similarly, the microneedle **294** has a conical outer wall **254** and **256**, with a similar top pointed surface at **298**. The other dimensions and features of the solid microneedle array **290** can be exactly the same as those features of the hollow microneedle array **280** of **FIG. 15**, or the dimensions may be different since this is for a different application.

It is clear from this paragraph, as well as Figs. 15A, 24, 26, and 29, that Sherman et al. teaches only the conventional design of solid microneedles that are pointed at the tip, presumably based on the assumption in the art that this is preferable. However, as noted in the first paragraph on page 8 of the present specification, providing the microneedles with a tip having the claimed surface area, rather than pointed tip, can improve structural integrity and avoid leaving fractured needle debris in the skin. This was not recognized or disclosed by Sherman et al.

Accordingly, Applicants believe that the present claims 1–8 and 17 are clearly novel over Sherman et al.

CONCLUSION

For the foregoing reasons, appellants respectfully submit that the Examiner has erred in rejecting this application and therefore request reversal.

Respectfully submitted,

August 3, 2010
Date

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CLAIMS APPENDIX

Listing of Claims

1. (Previously Presented) A microneedle device comprising:

a substrate comprising a first major surface; and

at least one microneedle projecting from the first major surface of the substrate, the at least one microneedle comprising a base proximate the first major surface of the substrate, wherein the at least one microneedle is tapered from the base to a flat tip distal from the base such that the at least one microneedle comprises a truncated tapered shape;

wherein the flat tip comprises a surface area measured in a plane aligned with the base of 20 square micrometers or more and 250 square micrometers or less.

2. (Original) A device according to claim 1, wherein the at least one microneedle comprises a plurality of microneedles.

3. (Original) A device according to claim 1, wherein the flat tip comprises a surface area of 100 square micrometers or less.

4. (Original) A device according to claim 1, wherein the flat tip comprises a surface area of 50 square micrometers or less.

5. (Original) A device according to claim 1, wherein the at least one microneedle comprises a height above the first major surface and a maximum base dimension, the height and the maximum base dimension ratio defining an aspect ratio, wherein the aspect ratio is 2:1 or more.

6. (Original) A device according to claim 1, wherein the at least one microneedle is formed of one or more polymers.

7. (Original)A device according to claim 1, wherein the base of the at least one microneedle comprises a base area of 900 square micrometers or more.

8. (Previously Presented) A microneedle device comprising:

a substrate comprising a first major surface; and

a plurality of microneedles projecting from the first major surface of the substrate, each microneedle of the plurality of microneedles comprising a base proximate the first major surface of the substrate, wherein each microneedle of the plurality of microneedles is formed of one or more polymers and is tapered from the base to a flat tip distal from the base such that each microneedle of the plurality of microneedles comprises a truncated tapered shape;

wherein the flat tip comprises a surface area measured in a plane aligned with the base of 20 square micrometers or more and 100 square micrometers or less;

wherein the base of each microneedle of the plurality of microneedles comprises a base area of 900 square micrometers or more;

and wherein each microneedle of the plurality of microneedles comprises a height above the first major surface and a maximum base dimension, the height and the maximum base dimension ratio defining an aspect ratio, wherein the aspect ratio is 3:1 or more.

9. – 16. (Cancelled)

17. (Original) A method of using a microneedle device, the method comprising:

providing a microneedle device according to claim 1;

contacting the skin on a patient with the at least one microneedle;

forcing the microneedle device against the skin.

18. - 40. (Cancelled)

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.